



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/713,632

11/13/2003

Lawrence M. Kauvar

388512011000

2417

25225 7590 01/28/2008
MORRISON & FOERSTER LLP
12531 HIGH BLUFF DRIVE
SUITE 100
SAN DIEGO, CA 92130-2040

EXAMINER

SHAW, AMANDA MARIE

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

01/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/713,632

Applicant(s)

KAUVAR ET AL.

Examiner

Amanda M. Shaw

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This action is in response to the amendment filed November 2, 2007. This action is made FINAL.

Claims 1-17 currently pending. Claims 1, 4-8, and 11-15 have been amended. Therefore Claims 1-17 will be addressed herein.

It is also noted that the Interview record is complete.

Withdrawn Rejections

2. The rejections made under 35 USC 102(b) in section 3 of the Office Action of August 20, 2007 are withdrawn in view of amendments made to the claims.

The rejections made under 35 USC 103(a) in sections 5-8 of the Office Action of August 20, 2007 are withdrawn in view of amendments made to the claims.

Specifically the Applicants amended independent claims 1 and 8 to recite a method wherein the region that is identified is no more than 1500 bases on a single copy of target nucleic acid. This was not taught by the previously applied prior art.

Claim Objections

The following is a new objection necessitated by amendment:

3. Claim 1 is objected to because of the following informalities: the recitation of "in an isolated a single copy" appears to have a typographical error. This could be amended to recite e.g., "on an isolated single copy".

Claim Rejections - 35 USC § 112 1st paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following are new rejections necessitated by amendment:

Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

In the instant case the specification does not appear to provide support for the amendment which recites a method "to identify a region of no more than 1500 bases". It is noted that the applicant points to the specification (para 32) for support. The specification states "if one assumes an apparent diameter of 400nm or radius of 200nm, a similar calculation would yield a spacing of approximately 1500 bases". The phrase approximately encompasses spacing which are greater than 1500 bases. Thus while the specification provides support for identifying a region of approximately 1500 bases, it does not provide specific support for identifying a region of no more than 1500 bases.

Claim Rejections - 35 USC § 112 2nd paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1634

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following are new rejections necessitated by amendment:

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that the goal of the method and the final step do not agree. The claims are drawn to a method to identify a region of no more than 1500 bases in an isolated single copy of a target nucleic acid. However, the claims recite the final step of interrogating a region to genotype the single copy the target nucleic acid. The steps listed in the method do not result in the identification of a region that is no more than 1500 bases. Therefore, it is unclear as to whether the claims are intended to be limited to methods for identifying a region of no more than 1500 bases in an isolated single copy of a target nucleic acid or methods for interrogating a region to genotype a single copy of target nucleic acid.

Claims 1 and 8 recite the limitation "said isolated target nucleic acid" in line 4. There is insufficient antecedent basis for this limitation in the claim because although the claim previously refers to "an isolated single copy of target nucleic acid" it does not refer to "an isolated target nucleic acid".

Claim 1 recites the limitation "said nucleic acid molecule" in line 12. There is insufficient antecedent basis for this limitation in the claim because the claims previously refer to different nucleic acid molecules i.e., target nucleic acid molecules

Art Unit: 1634

and non target nucleic acid molecules. Therefore it is unclear which nucleic acid molecules are being referred to in line 12.

Claims 4-6 and 11-13 recite the limitation "said first and second oligonucleotides". There is insufficient antecedent basis for this limitation in the claim because although claims 1 and 8 previously refer to "a first oligonucleotide" and a "second oligonucleotide", the claims do not refer to "first and second oligonucleotides".

Claim 7 recites the limitation "said immediate upstream and downstream sequences". There is insufficient antecedent basis for this limitation in the claim because although claim 1 previously refers to "a sequence immediately upstream said region" and a "sequence immediately downstream said region", the claims do not refer to "immediate upstream and downstream sequences".

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following are new rejections necessitated by amendment:

Art Unit: 1634

7. Claims 1, 4-5, 7-8, 11-12, 14-15, and 17 are rejected under 35 U.S.C. 102(a) as being anticipated by Cai (WO/0190418 Pub 11/29/2001).

Regarding Claims 1 and 8 Cai teaches a method for rapid haplotyping which uses a single molecule approach based on the simultaneous detection of two or more target sites on a segment of nucleic acid, wherein the two or more target sites are labeled with separate distinguishable luminescent hybridization probes (page 8, lines 13-19). In the instant case the nucleic acids of Cai are being interpreted as isolated since they have been extracted from a cell. The sample is also being interpreted as comprising target nucleic acid (i.e., regions where the probes bind) and non target nucleic acid (i.e., regions where the probes do not bind). In one example described by Cai the two oligonucleotide probes are hybridized to two target sites that are approximately 40bp apart from one another (page 21, line 6 to page 22, line 25). Thus Cai teaches a method wherein the first oligonucleotide probe binds immediately upstream of the 40 bp region to be identified and the second oligonucleotide probe binds immediately downstream of the 40 bp region to be identified wherein the region bracketed by the probes is no more than 1500 bases. Cai further teaches that the two oligonucleotide probes can be distinguishable labeled with nano-particles (page 9, lines 4-12). In the instant case the nano-particles taught by Cai are being applied as particulate labels because they are particulate and they are labels. As described in Example 1 the paired probes having the first and second labels hybridize to the target to provide the labels as points separated by space. This separation in space can be observed using an ultra sensitive luminescence confocal microscope. Luminescence

Art Unit: 1634

emission from two luminescent probes that are hybridized to single DNA fragments are recorded in two separate detection channels, thus the labels can be observed individually. The co-localization of the two hybridization probes on the same DNA haploid is signaled by the simultaneous detection of luminescence in both channels. By performing a cross correlation between the detectors, one determines whether the DNA is illuminated by the light beams contains one or both hybridization probes (page 11, line 28 to page 12, line 5). Thus Cai teaches a method of contacting a sample with first and second probes which bracket a region and observing by microscopy the presence or absence of each member of any pairs of the first and second particulate labels as separate points in space, whereby the presence of pairs identifies the region. Cai further teaches that this method can be used for haplotyping which is interpreted as a method of genotyping since it determines the allele present at specific nucleotide positions. In some embodiments Cai also teaches that the sequence of target region known (page 21, lines 28-29).

Regarding Claims 4 and 11 Cai teaches a method wherein the first and second oligonucleotides are peptide nucleic acids (page 9, lines 21-22).

Regarding Claims 5 and 12 Cai teaches a method wherein the target is single stranded and the first and second probes are complementary to sequences upstream and downstream sequences bracketing the region (page 18, lines 11-20 and Fig 3A).

Regarding Claims 7 and 14 Cai teaches that is possible use more than two distinct probes to simultaneously detect additional genetic marker sites by inserting additional spectral filters and concomitant detectors for the wavelengths of interest

(page 12, lines 6-10). Thus Cai teaches a method that can be performed simultaneously on a multiplicity of targets using a multiplicity of probes having different particulate labels wherein the probes bind to a multiplicity of upstream and downstream sequences bracketing a multiplicity of regions.

Regarding Claim 15 and 17 Cai teaches the method can be used for analysis of human SNPs (page 21, line 2). Thus Cai teaches a method wherein the target nucleic acid of known sequence is isolated from an organism, wherein the organism is a human.

8. Claims 1, 4-5, 7-8, 11-12, 14-15, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Cai (US 2006/0008799 Filed 5/21/2001 which claims priority to 60206512 filed May 22, 2000).

Regarding Claims 1 and 8 Cai teaches a method for rapid haplotyping which uses a single molecule approach based on the simultaneous detection of two or more target sites on a segment of nucleic acid, wherein the two or more target sites are labeled with separate distinguishable luminescent hybridization probes (para 0029). In the instant case the nucleic acids of Cai are being interpreted as isolated since they have been extracted from a cell. The sample is also being interpreted as comprising target nucleic acid (i.e., regions where the probes bind) and non target nucleic acid (i.e., regions where the probes do not bind). In one example described by Cai the two oligonucleotide probes are hybridized to two target sites that are approximately 40bp apart from one another (Example 1). Thus Cai teaches a method wherein the first

Art Unit: 1634

oligonucleotide probe binds immediately upstream of the 40 bp region to be identified and the second oligonucleotide probe binds immediately downstream of the 40 bp region to be identified wherein the region bracketed by the probes is no more than 1500 bases. Cai further teaches that the two oligonucleotide probes can be distinguishable labeled with nano-particles (para 0032). In the instant case the nano-particles taught by Cai are being applied as particulate labels because they are particulate and they are labels. As described in Example 1 the paired probes having the first and second labels hybridize to the target to provide the labels as points separated by space. This separation in space can be observed using an ultra sensitive luminescence confocal microscope. Luminescence emission from two luminescent probes that are hybridized to single DNA fragments are recorded in two separate detection channels, thus the labels can be observed individually. The co-localization of the two hybridization probes on the same DNA haploid is signaled by the simultaneous detection of luminescence in both channels. By performing a cross correlation between the detectors, one determines whether the DNA is illuminated by the light beams contains one or both hybridization probes (para 0046). Thus Cai teaches a method of contacting a sample with first and second probes which bracket a region and observing by microscopy the presence or absence of each member of any pairs of the first and second particulate labels as separate points in space, whereby the presence of pairs identifies the region. Cai further teaches that this method can be used for haplotyping which is interpreted as a method of genotyping since it determines the allele present at specific nucleotide

Art Unit: 1634

positions. In some embodiments Cai also teaches that the sequence of target region known (Example 1).

Regarding Claims 4 and 11 Cai teaches a method wherein the first and second oligonucleotides are peptide nucleic acids (para 32).

Regarding Claims 5 and 12 Cai teaches a method wherein the target is single stranded and the first and second probes are complementary to sequences upstream and downstream sequences bracketing the region (para 0071 and Fig 3A).

Regarding Claims 7 and 14 Cai teaches that is possible use more than two distinct probes to simultaneously detect additional genetic marker sites by inserting additional spectral filters and concomitant detectors for the wavelengths of interest (para 0047). Thus Cai teaches a method that can be performed simultaneously on a multiplicity of targets using a multiplicity of probes having different particulate labels wherein the probes bind to a multiplicity of upstream and downstream sequences bracketing a multiplicity of regions.

Regarding Claim 15 and 17 Cai teaches the method can be used for analysis of human SNPs (para 0080). Thus Cai teaches a method wherein the target nucleic acid of known sequence is isolated from an organism, wherein the organism is a human.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1634

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following are new rejections necessitated by amendment

10. Claims 2-3 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cai (WO/0190418 Pub 11/29/2001) in view of Kauvar (WO 00/14545 Pub 3/2000).

The teachings of Cai are presented above.

Regarding Claims 2 and 9 Cai does not teach a method wherein the first and second particulate labels comprise first and second fluorophores. Regarding Claim 3 Cai does not teach a method wherein said first and second fluorophores are distinguishable from one another. Regarding Claim 10 Cai does not teach a method wherein said first and second fluorophores are the same as each other.

However, Kauvar teaches particulate supports that are bound to at least two distinguishable fluorophores (Abstract). Specifically Kauvar teaches a particulate that is

Art Unit: 1634

bound to 7 red fluorophores and 3 blue fluorophores (See Fig 2). Thus Kauvar teaches a method wherein the particulate labels comprise first and second fluorophores. In the instant case the red fluorophores and the blue fluorophores emit light at different wavelengths therefore they are considered to be distinguishable from one another.

Kauvar also teaches particulates that have different hues. For example Kauvar teaches a particulate that is bound to 7 red fluorophores and 3 blue fluorophores will have a different hue than a particulate that is bound to 6 red fluorophores and 4 blue fluorophores. Thus Kauvar teaches particulates wherein the first fluorophores are the same because they are both red and the second fluorophores are the same because they are both blue.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Cai by using particulate labels comprising first and second fluorophores as suggested by Kauvar. In the instant case all of the claimed elements are taught in the prior art and one of skill in the art could have combined the elements as claimed and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Art Unit: 1634

11. Claims 6 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cai (WO/0190418 Pub 11/29/2001) in view of Nie et al (US Patent 6060242).

The teachings of Cai are presented above.

While Cai teaches that the probes can be a PNA, Cai does not teach a method wherein the target nucleic acid is double stranded and the probe forms a triplex with the target nucleic acid.

However Nie et al teaches a method which uses PNA probes which are able to recognize dsDNA and form triplex complexes with dsDNA (Column 3, lines 24-27 and lines 38-39).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Cai by using PNA probes that form triplexes with double stranded target nucleic acid as suggested by Nie. In the instant case Cai teaches a method of haplotyping single stranded nucleic acid while Nie teaches a method of using PNA probes which are able to recognize dsDNA and form triplex complexes with dsDNA. Thus by using the PNA probes of Nie in the method of Cai, one could eliminate the step of denaturing double stranded nucleic acid prior to hybridization with the PNA probes. In the instant case all of the claimed elements are known in the art and would could have combined these methods and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

12. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cai (WO/0190418 Pub 11/29/2001) in view of Spies (US Patent 5736334 Issued 1998).

The teachings of Cai are presented above.

Regarding Claim 16 Cai does not teach that the target nucleic acid is derived from an organism wherein the organism is an infectious agent.

However Spies teaches a method wherein Hepatitis B viral DNA is detected using two probes (Column 5, lines 45-56). Thus Spies teaches a method wherein the target nucleic acid is derived from an organism wherein the organism is an infectious agent.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Cai by detecting target DNA from an organism that is an infectious agent in order to have achieved the benefits set forth by Spies of providing a method which enables one to detect hepatitis B virus present in a sample.

13. Claims 2-3 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cai (US 2006/0008799 Filed 5/21/2001 which claims priority to 60206512 filed May 22, 2000) in view of Kauvar (WO 00/14545 Pub 3/2000).

The teachings of Cai are presented above.

Art Unit: 1634

Regarding Claims 2 and 9 Cai does not teach a method wherein the first and second particulate labels comprise first and second fluorophores. Regarding Claim 3 Cai does not teach a method wherein said first and second fluorophores are distinguishable from one another. Regarding Claim 10 Cai does not teach a method wherein said first and second fluorophores are the same as each other.

However, Kauvar teaches particulate supports that are bound to at least two distinguishable fluorophores (Abstract). Specifically Kauvar teaches a particulate that is bound to 7 red fluorophores and 3 blue fluorophores (See Fig 2). Thus Kauvar teaches a method wherein the particulate labels comprise first and second fluorophores. In the instant case the red fluorophores and the blue fluorophores emit light at different wavelengths therefore they are considered to be distinguishable from one another. Kauvar also teaches particulates that have different hues. For example Kauvar teaches a particulate that is bound to 7 red fluorophores and 3 blue fluorophores will have a different hue than a particulate that is bound to 6 red fluorophores and 4 blue fluorophores. Thus Kauvar teaches particulates wherein the first fluorophores are the same because they are both red and the second fluorophores are the same because they are both blue.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Cai by using particulate labels comprising first and second fluorophores as suggested by Kauvar. In the instant case all of the claimed elements are taught in the prior art and one of skill in the art

Art Unit: 1634

could have combined the elements as claimed and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

14. Claims 6 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cai (US 2006/0008799 Filed 5/21/2001 which claims priority to 60206512 filed May 22, 2000) in view of Nie et al (US Patent 6060242).

The teachings of Cai are presented above.

While Cai teaches that the probes can be a PNA, Cai does not teach a method wherein the target nucleic acid is double stranded and the probe forms a triplex with the target nucleic acid.

However Nie et al teaches a method which uses PNA probes which are able to recognize dsDNA and form triplex complexes with dsDNA (Column 3, lines 24-27 and lines 38-39).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Cai by using PNA probes that form triplexes with double stranded target nucleic acid as suggested by Nie. In the instant case Cai teaches a method of haplotyping single stranded nucleic acid while Nie teaches a method of using PNA probes which are able to recognize dsDNA and form triplex complexes with dsDNA. Thus by using the PNA probes of Nie in the method of Cai, one could eliminate the step of denaturing double stranded nucleic acid prior to hybridization with the PNA probes. In the instant case all of the claimed elements are

Art Unit: 1634

known in the art and would could have combined these methods and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

15. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cai (US 2006/0008799 Filed 5/21/2001 which claims priority to 60206512 filed May 22, 2000) in view of Spies (US Patent 5736334 Issued 1998).

The teachings of Cai are presented above.

Regarding Claim 16 Cai does not teach that the target nucleic acid is derived from an organism wherein the organism is an infectious agent.

However Spies teaches a method wherein Hepatitis B viral DNA is detected using two probes (Column 5, lines 45-56). Thus Spies teaches a method wherein the target nucleic acid is derived from an organism wherein the organism is an infectious agent.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Cai by detecting target DNA from an organism that is an infectious agent in order to have achieved the benefits set forth by Spies of providing a method which enables one to detect hepatitis B virus present in a sample.

Conclusion

Art Unit: 1634

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1634

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner
Art Unit 1634


JULIET C. SWITZER
PRIMARY EXAMINER